Evaluation of the Minority HIV/AIDS Research Initiative (MARI): 2003-Present Under Generic Information Collection: Formative Research and Tool Development

OMB No. 0920-0840

Supporting Statement A

June 13, 2024

Contact Information:

Kimberly Evans, PhD, MPH, CPH | Epidemiologist
LCDR, U.S. Public Health Service
HIV Research Branch | Division of HIV Prevention

National Center for HIV, Viral Hepatitis, STD, and TB Prevention | Centers for Disease Control and Prevention

Phone: 404-639-1440 Email: <u>xli5@cdc.gov</u>

Table of Contents

Section

A. Justification

- 1. Circumstances Making the Collection of Information Necessary
- 2. Purpose and Use of the Information Collection
- 3. Use of Improved Information Technology and Burden Reduction
- 4. Efforts to Identify Duplication and Use of Similar Information
- 5. Impact on Small Businesses or Other Small Entities
- 6. Consequences of Collecting the Information Less Frequently
- 7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
- 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
- 9. Explanation of Any Payment or Gift to Respondents
- 10. Protection of the Privacy and Confidentiality of Information Provided by Respondents
- 11. Institutional Review Board (IRB) and Justification for Sensitive Questions
- 12. Estimates of Annualized Burden Hours and Costs
- 13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers
- 14. Annualized Cost to the Federal Government
- 15. Explanation for Program Changes or Adjustments
- 16. Plans for Tabulation and Publication and Project Time Schedule
- 17. Reason(s) Display of OMB Expiration Date is Inappropriate
- 18. Exceptions to Certification for Paperwork Reduction Act Submissions

Exhibits

Exhibit 12.A	Estimated Annualized Burden Hours
Exhibit 12.B	Estimated Annualized Burden Costs
Exhibit 14.A	Estimated Cost to the Government

Attachments

- Att 1 Authorizing Legislation
- Att 2 Survey
- Att 3 Survey Screenshots
- Att 4 Recruitment Email
- Att 5 Example Consent Form
- Att 6 Privacy Impact Assessment
- Att 7 Project Determination

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests approval of a generic information collection, "Evaluation of the Minority HIV/AIDS Research Initiative (MARI): 2003-Present" under the umbrella Generic, Formative Research and Tool Development (OMB#0920-0840, exp. 03/31/2027). The information collection supports formative research and program evaluation for the refinement of the Minority HIV/AIDS Research Initiative.

The National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), which also includes the Division of HIV Prevention (DHP) has implemented the Minority HIV/AIDS Research Initiative (MARI) since 2003 to build capacity for HIV prevention and treatment research in racial/ethnic minority communities disproportionately affected by HIV and among racial/ethnic minority investigators historically underrepresented in research. This request for generic clearance to conduct formative research to evaluate the MARI program will assess the overall impact of MARI on funded recipients' careers as an early-career HIV training program and on the impact of their research within communities of color disproportionately affected by HIV. The formative research and tool development activities will occur among only previously funded MARI recipients and will guide the refinement of the MARI program. This formative research is beneficial in:

- assessing the impact of MARI funding on early-career investigators' careers and research portfolios;
- understanding the impact of MARI funding on research and health outcomes within communities of color disproportionately affected by HIV; and

• understanding how MARI can improve as a training program to better support early-career investigators from underrepresented racial/ethnic backgrounds and their research.

Background

Since 2003, the CDC's Division of HIV Prevention has implemented the Minority HIV/AIDS Research Initiative (MARI) to build capacity for HIV prevention and treatment research in racial/ethnic minority communities disproportionately affected by HIV¹ and among racial/ethnic minority investigators historically underrepresented in research². MARI provides support for intensive research training and career development under the guidance of an experienced local mentor in HIV prevention research. This leads to promising and culturally competent epidemiologic, behavioral, and implementation science research tailored for communities of color disproportionately affected by HIV. To date, MARI has funded, trained, and mentored 42 early-career investigators across the U.S. and has provided seed funding within racial/ethnic, sexual, and gender minority (e.g., men who have sex with men and transgender) communities³-5.

MARI is a unique federal initiative, and an evaluation of the program could yield rich results to assess the impact it has had on communities of color for the past two decades and on researchers' careers. Results can also inform the future direction of MARI as an early-career training program for equitable funding and research opportunities for communities of color disproportionately affected by HIV-related disparities and for equitable training opportunities for racial/ethnic minority investigators who are often marginalized⁶.

Overall, the evaluation of MARI is intended to provide information that will increase the success of the MARI training program and the development of research to reduce HIV-related disparities among racial/ethnic minority communities. This ongoing data collection activity benefits the Federal Government by providing the CDC with data to determine how to best manage and improve the MARI training program, train a diversified workforce, and improve the health of communities disproportionately impacted by HIV.

Data collection for this project is authorized under 42 U.S.C. 241, Chapter 6a - Public Health Service; Subchapter Ii - General Powers and Duties Part A - Research and Investigations (**Attachment 1**).

This data collection is planned as a cross-sectional survey (**Attachment 2**), including open-ended questions to evaluate MARI programming since inception based on the participating investigators' points of view. The survey will contain questions to assess the overall impact of MARI on funded recipients' careers as an early-career HIV training program and on the impact of their research within communities of color disproportionately affected by HIV. This evaluation addresses health equity by understanding the impact MARI had on communities of color and on MARI-funded recipients' careers who are largely from racial and ethnic minority backgrounds and, who historically in the U.S., have not received equitable training and funding research opportunities.

The information collection activities are limited to formative work that will result in the evaluation of the MARI training program. The types of information collection activities included in this generic package are:

1) Quantitative surveys as formative research to evaluate the MARI program. The surveys will be administered to individual previously funded MARI recipients through electronic surveys.

The survey tool to collect the data is provided in **Attachment 2**. The information collected may contain personally identifiable information such as name, gender, and race/ethnicity of individuals. Personally identifiable information will be kept in a separate location and accessible only to the CDC staff and contractors. All data will be stored for six years on the CDC's MARI shared drive folder. This folder is on the secure CDC server, and access is only granted to specific persons who work on MARI activities. After six years, the data will be archived according to the guidance set forth by CDC Records Management Policy, Policy # CDC-GA-2005-07 (updated 9/14/2021).

The information collected for the project will be maintained or stored locally under strict access controls limited to the local project leader/manager or his/her designate. Under no circumstances will an individual be identified using a combination of variables such as gender, race, and/or other descriptors.

2. Purpose and Use of Information Collection

The MARI program has sought to build capacity for HIV prevention and treatment research in racial/ethnic minority communities disproportionately affected by HIV and among racial/ethnic minority investigators historically underrepresented in research. This request for generic clearance to evaluate the MARI program will inform the overall impact of MARI on funded recipients' careers as an early-career HIV training program and on the impact of their research within communities of color disproportionately affected by HIV and will guide the refinement of the MARI program for future implementation. The quantitative surveys will provide the information to make the refinements necessary to ensure MARI is an effective training program for early-career investigators and impacts racial/ethnic minority communities disproportionately affected by HIV.

None of the proposed activities intend to produce results that can be generalized beyond the scope of the MARI study. This Generic gives us the opportunity to obtain feedback necessary to evaluate the MARI program for current and future implementation.

3. Use of Improved Information Technology and Burden Reduction

MARI investigators will be invited to participate in the survey by a recruitment email (**attachment 4**). Data will be collected using approved CDC software (e.g., SurveyMonkey, Microsoft Forms). The use of an electronic survey (**Attachment 3**) will reduce burden on the public respondents because this approach ensures data quality but decreases respondent burden with built-in skip logic.

4. Efforts to Identify Duplication and Use of Similar Information

There is no overlap or duplication of specific projects from NCHHSTP with the MARI evaluation. NCHHSTP has verified through RegInfo.gov that there are no other federal generic collections that duplicate the evaluation of MARI included in this request.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in the data collection activities.

6. Consequences of Collecting the Information Less Frequently

This generic clearance covers a single data collection activity. The data collection will be time-limited and conducted only once. The data collection activity will not take longer than 1 year to complete from inception of information collection to the first report of findings. Collecting this information less frequently could impact trend results over a period of time, but it is not necessary for this project.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agencies

The Federal Register notice was published for the Generic clearance on September 26, 2023, Vol. 88, No. 185 pp. 66001. One public non-substantive comment was received. The standard CDC response was sent to say thank you for your interest.

The following CDC employees were consulted for the development of this request:

Heather Tevendale, PhD	Damian Denson, PhD, MPH
Associate Chief for Behavioral Science	Epidemiologist
HIV Research Branch	HIV Research Branch
NCHHSTP, CDC	NCHHSTP, CDC
1600 Clifton Road NE, H24-5	1600 Clifton Road NE, H24-5
Atlanta, GA 30333	Atlanta, GA 30333
(770) 488-6147	(404) 639-6125
Email: hrx@cdc.gov	Email: DDenson1@cdc.gov
Constance Bonds, MPH, MPA	Natasha Ptomey, MPH
NCHHSTP PRA Coordinator	OMB PRA Contact
CDC/NCHHSTP	ORAU
1600 Clifton Road NE, MS-E07	CDC/NCHHSTP/DHAP
Atlanta, GA 30333	1600 Clifton Road NE, MS-D21
(404) 718-8548	Atlanta, GA 30333
Email: cbonds@cdc.gov	(404) 639-1569

9. Explanation of Any Payment or Gift to Respondents

No token of appreciation will be given to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.

The Privacy Officer for CDC / ATSDR has assessed this package for applicability of 5 U.S.C. § 552a (attachment 6). The Privacy Act is applicable because personally identifiable information (PII) is being collected under this CDC-funded activity. All participants will review and sign an informed consent form (Attachment 5) prior to participating in the survey. The informed consent outlines that CDC MARI staff will keep the information collected private and secure. CDC MARI staff will maintain files for each participant's response. All collected data will be stored on a CDC secured server on a MARI shared drive folder.

Data will be kept private to the extent allowed by law.

All CDC permanent employees and contractors who are involved in MARI activities will be required to attend annual security and privacy training.

Electronic data collection and data management systems used for this evaluation will comply with the current encryption security standards from the CDC. Each individual request under this generic clearance will provide adequate descriptions of information systems that will be used in their study.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

CDC NCHHSTP has determined that the data/ information collection is not research involving human subjects and the information collection submitted under this generic clearance does not require IRB approval. The NCHHSTP research project determination form is attached (**Attachment** 7).

Sensitive Questions

The evaluation of MARI covered by this information collection request involves sexual gender identity, race/ethnicity, and that may be viewed as sensitive by a portion of respondents. The reasons for collection of sensitive information and their application for the improvement of CDC's MARI will be addressed in specific requests. The procedures used to obtain consent and the content of the consent form will also be explained and justified. In no case will a participant's social security number be obtained.

Collection of sensitive data will be used to understand barriers to engaging in protective behaviors and to using prevention services.

A.12. Estimates of Annualized Burden Hours and Costs

The annualized response burden is estimated at 25 hours. Exhibits A.12.A provides details about how this estimate was calculated. Timings were conducted during the instrument development process to support the overall burden per respondent. A participant reading and signing the consent form (**Attachment 5**) is estimated to take 5 minutes. Participation in the survey (**Attachment 2**) is estimated to take 30 minutes.

Exhibit A.12. Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Hours Per Response	Total Response Burden (Hours)
MARI Investigators	Consent	42	1	5/60	4
	Forms (Att 5)				
MARI Investigators	Survey (Att 2)	42	1	30/60	21
Total					25

A.12.B Estimated Annualized Costs

This collection will involve 100% of former MARI funded investigators. The annualized cost to the respondent is segmented accordingly in Exhibit A.12.B.

The United States Bureau of Labor Statistics' employment and wages estimates from May, 2023 (https://www.bls.gov/oes/current/oes193022.htm) were used to estimate the hourly wage rate for the general public for the purpose of this request. Each project will have cost specific to the category of the respondents. Because it is not known what the wage rate category will be appropriate for the specific projects (or even whether they will be employed at all), the figure of \$32.05 per hour was used as an estimate of average hourly wage across the country.

Exhibit A.12.B. Annualized Cost to Respondents

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Consent Forms	4	\$32.05	\$128.20
Surveys	21	\$32.05	\$673.05
Total			\$801.25

A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

CDC does not anticipate providing start up or other related costs to private entities.

A.14. Annualized Costs to the Government

The annualized cost to the government is \$20,580.50. Generally, each development activity will involve participation of at least one CDC project officer (GS- 14 level) who will be responsible for the project design, providing project oversight, and analysis and dissemination of the results. The CDC project officer will provide remote technical assistance involved in implementing the data collection. A CDC data manager's (typically a contractor equivalent to GS-11) time may also be required.

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government		
	CDC Project Officer (GS-14, 0.10 FTE)	\$12,913.40
	CDC Data Manager (GS-11, 0.10 FTE)	\$7,667.10
	Subtotal, Direct costs	\$20,580.50
	TOTAL COST TO THE GOVERNMENT	\$20,580.50

A.15. Explanation for Program Changes or Adjustments

There are no changes to the burden from the burden shown in the current inventory.

A.16. Plans for Tabulation and Publication and Project Time Schedule

The data collection will be time-limited and conducted only once. The data collection activity will not take longer than 1 year to complete from inception of information collection to the first report of findings. The proposed timeline for this data collection activity is below.

Activity	Time Schedule
Develop a list of MARI Investigators contact information	1-2 weeks after OMB approval
Administer MARI survey to MARI investigators via email	2-4 weeks after OMB approval
Collect MARI survey responses	1 month - 3 months after OMB approval
Analyze and report on MARI survey findings	3-12 months after OMB approval

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

- 1. Centers for Disease Control and Prevention. *HIV Surveillance Report*, 2021; vol. 34. http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Published May 2023. Accessed March 18, 2024.
- 2. Fitzpatrick, L. K., Sutton, M., & Greenberg, A. E. (2006). Toward eliminating health disparities in HIV/AIDS: the importance of the minority investigator in addressing scientific gaps in Black and Latino communities. *Journal of the National Medical Association*, *98*(12), 1906–1911.
- 3. Sutton, M. Y., Lanier, Y. A., Willis, L. A., Castellanos, T., Dominguez, K., Fitzpatrick, L., & Miller, K. S. (2013). Strengthening the network of mentored, underrepresented minority scientists and leaders to reduce HIV-related health disparities. *American journal of public health*, 103(12), 2207–2214. https://doi.org/10.2105/AJPH.2013.301345
- 4. Sutton, M. Y., Martinez, O., Brawner, B. M., Prado, G., Camacho-Gonzalez, A., Estrada, Y., Payne-Foster, P., Rodriguez-Diaz, C. E., Hussen, S. A., Lanier, Y., van den Berg, J. J., Malavé-Rivera, S. M., Hickson, D. A., & Fields, E. L. (2021). Vital Voices: HIV Prevention and Care Interventions Developed for Disproportionately Affected Communities by Historically Underrepresented, Early-Career Scientists. *Journal of racial and ethnic health disparities*, 8(6), 1456–1466. https://doi.org/10.1007/s40615-020-00908-2
- 5. Evans, K. N., Martinez, O., King, H., van den Berg, J. J., Fields, E. L., Lanier, Y., Hussen, S. A., Malavé-Rivera, S. M., Duncan, D. T., Gaul, Z., & Buchacz, K. (2023). Utilizing Community Based Participatory Research Methods in Black/African American and Hispanic/Latinx Communities in the US: The CDC Minority HIV Research Initiative (MARI-Round 4). *Journal of community health*, 48(4), 698–710. https://doi.org/10.1007/s10900-023-01209-5
- 6. Nguyen M, Chaudhry SI, Desai MM, Dzirasa K, Cavazos JE, Boatright D. Gender, Racial, and Ethnic Inequities in Receipt of Multiple National Institutes of Health Research Project Grants. *JAMA Netw Open.* 2023;6(2):e230855. doi:10.1001/jamanetworkopen.2023.0855